

1.0 PURPOSE

- 1.1 The purpose of this procedure is to ensure that all operators, maintenance, sterilization sciences personnel, applicable controls engineers and supervisory personnel have a clear understanding of the safety systems in the Sterilization Department. These individuals are to be aware of the monitoring devices present, what safety systems are automatic, what systems must be activated manually and what is required prior to modification or creation of a sterilization cycle for testing purposes to prevent a flammability condition.
- 1.2 This document provides the tools to eliminate the hazards associated with EO Sterilization as defined by SOP-MD-2005638, Ethylene Oxide Program.
- 1.3 This document is prepared in accordance with regulations and standards identified in the current version of the B.Braun Quality Policy Manual (COP-QPM-8000001).

2.0 SCOPE

- 2.1 This procedure applies to EO Sterilization operations located at the Allentown, PA manufacturing facility.
- 2.2 Ownership of this document belongs to Sterilization.
- 2.3 Approval of this procedure is required from the following personnel or their direct report or superior:
 - 2.3.1 Director, Quality PA
 - 2.3.2 Associate Director, Sterilization
 - 2.3.3 Manager, Environmental, Health, Safety & Security
- 2.4 Training for this document is required for applicable personnel from the following functional areas:
 - 2.4.1 Sterilization
 - 2.4.2 Environmental, Health, Safety & Security
 - 2.4.3 Applicable Controls Engineers

3.0 REFERENCES

- 3.1 COP-QPM-8000001, Quality Policy Manual
- 3.2 SOP-MD-2005638, Ethylene Oxide Program
- 3.3 SOP-MD-2020478, Flammability Chart Ethylene Oxide

4.0 MONITORING

- 4.1 **EO Monitoring System** – The system consists of indicator lights at the entrance to each area being monitored. Monitored areas include: EO gas room, scrubber room, all sterilization bays, loading and unloading areas, aeration rooms and aeration loading area. A green light means the area can be entered without SCBA (self contained breathing apparatus). A yellow light means the area can be entered without SCBA for up to 15 minutes. A red light means the area cannot be entered unless SCBA is worn.
- 4.2 **Ethylene Oxide Monitors** – Battery powered portable units which sample the air in ppm. These units give an instantaneous readout.
- 4.3 **EO Passive Monitors** – Passive monitoring badges worn by employees based on EH&S

Compliance monitoring schedule to obtain TWA (time weighted average) & STEL (short term exposure limit) results as per SOP-MD-2005638.

5.0 VENTILATION

- 5.1 The Sterilization Department has four exhaust systems that are considered critical to the safe operation of the department. These systems are as follows:
- 5.1.1 **Sterilizer Bay Exhaust** – Located in each sterilizer bay. Whenever the outside temperature is greater than 55°F, the bay exhausts will be on. When the outside temperature is less than 55°F the bay exhausts will cycle on and off allowing them to operate a specified number of minutes/hour. When unloading a chamber, the operators can force the bay exhaust to turn on. The bay exhaust systems for chambers 6 and 7 are always on, regardless of the outside temperature.
 - 5.1.2 **ETO Storage Room Exhaust** – Located behind some of the drum stations and on the floor. Exhaust is always on.
 - 5.1.3 **Chamber Rear Exhaust** – Automatically activates at the end of cycle. Air flow keeps EO-laced air away from the operator.
 - 5.1.4 **ETO Piping Exhaust** – Activated 100% of the time. The gas room pressure is always kept lower than the air supply to the ETO piping systems, thus drawing air over the ETO piping supplies back to the gas room at all times.

6.0 EMERGENCY SYSTEMS

- 6.1 **Water Deluge System** – One sprinkler head is located over every drum of ethylene oxide connected to the sterilizer piping. This system is activated by a mushroom style actuator located adjacent to the Control Room door.
- 6.2 **Fire Extinguishers** – Located throughout the sterilization area.
- 6.3 **Sprinkler System** – Located throughout the sterilization area. The sprinkler system is triggered by excessive heat.
- 6.4 **Emergency Shutoff** – Located on the wall adjacent to the Control Room entrance. When the breaker is switched, all power to the sterilization panels will be halted and all air flow to the controlling valves will be stopped.

7.0 PROTECTION

- 7.1 Self-Contained Breathing Apparatus (**SCBA**) – Located in the unloading area. A self-contained breathing apparatus must be utilized when EO concentration exceeds 5ppm (when EO Monitoring system lights are RED). One tank is good for 30 minutes.

8.0 STERILIZATION CYCLE MODIFICATION/CREATION – FLAMMABILITY PREVENTION

- 8.1 Cycle modification or creation is required for test purposes associated with maintenance activities, controls activities or cycle study work.
 - 8.1.1 Cycle modifications and/or a new cycle can be created by sterilization maintenance, sterilization engineers, sterilization sciences personnel and/or Controls Engineers.
- 8.2 The modification or creation of a cycle which allows for the presence of oxygen while EO is still present can present a flammable or explosive condition within the chamber.

- 8.3 Any cycle where the injection of EO is completely removed or never added as a cycle step does not present any flammability risk.
- 8.4 Prior to modifying or creating a cycle in the Control system, a flammability evaluation of the cycle must be conducted and approved. This only needs to be done one time for a given cycle change or creation. No flammability evaluation is required when removing EO injection or building a cycle where EO injection is not a step in the process as in section 8.3. Also, no flammability diagram is necessary when changing the injection rates, evacuation rates and dwell/exposure times or an already approved cycle.
- 8.5 Using SOP-MD-2020478, enter purpose, chamber temperature and chamber volume, list the cycle steps or phase of cycle, pressure requirements and length of time for each phase.
 - 8.5.1 A potential issue with pressure set-point and associated phase will be highlighted in red. For example after a vacuum phase to 9.0 psia an inject phase is entered with a pressure of 8.0 psia, the pressure set-point will highlight red indicating an invalid pressure rise.
 - 8.5.2 Note: Chamber temperature and volume are only required to obtain an accurate theoretical EO usage, Nitrogen usage and %RH. These cells will not impact the flammability diagram.
- 8.6 The flammability chart will automatically populate with each step added.
- 8.7 Once complete, the chart, must show that the line does not touch or cross over into the flammable area of the chart to be considered acceptable.
- 8.8 Print the chart, sign and submit to Sterilization Sciences/Engineering management or designee for approval.
 - 8.8.1 The flammability chart will be filed with Sterilization Sciences and electronically filed in the electronic document system, BDocs as supporting data.
 - 8.8.2 When running a modified cycle for maintenance, controls work or cycle study work, place a copy of the cycle in the Paperwork bin for the associated chamber for which the cycle is being run as notice to the operators.
- 8.9 No cycle change or new cycle will be accepted for use if it considered flammable at any stage of the process.
- 8.10 No cycle modifications or new cycles will be run for routine production without an appropriate approved change control in accordance with company policy.

END OF SOP-MD-2000011

CHANGE HISTORY

<u>RATIONALE SUMMARY</u>			
Updated document to remove references to the old Vulcain EO monitoring system.			
<u>CHANGE SUMMARY – Updated to Current Practices</u>			
<u>SECTION/PAGE</u>	<u>DESCRIPTION</u>		
1.2 / 1	Corrected the SOP number (SOP-MD-2005638 instead of SOP-MD-2005838).		
2.3.3 / 1	Title changed from Manager, Environmental Health & Safety to Manager, Environmental, Health, Safety & Security		
2.4.2 / 1	Functional area changed from Environmental Health & Safety to Environmental, Health, Safety & Security		
3 / 1	Added documents to the References section.		
4 / 1&2	Separated the incorrect double-reference to section 4.		
4.1 / 1	Removed the word Vulcain. Added other areas that will be monitored by the EO monitoring system.		
4.3 / 2	Added the acronym definitions for TWA and STEL.		
5.1.1 / 2	Clarified the times when the bay exhaust systems operate.		
5.1.4 / 2	Added further description details for the ETO piping exhaust.		
7.1 / 2	Replaced the word Vulcain with EO Monitoring.		
All	Minor grammatical/spelling/spacing corrections.		

<u>SUPPORTING DATA (Y/N)</u>	N	<u>DOCUMENT NAME OF SUPPORTING DATA</u>	N/A
N/A			

<u>ADD / DELETE KEYWORDS FOR THIS DOCUMENT (Y/N)</u>		N
<u>ADD:</u>	N/A	
<u>DELETE:</u>	N/A	

<u>RELATED DOCUMENTS TO THIS VERSION (Y/N)</u>		N
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N/A	N/A	N/A
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